

drugs and biologicals that are furnished as part of an outpatient hospital service:

(1) *Orphan drugs.* A drug or biological that is used for a rare disease or condition and has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(2) *Cancer therapy drugs and biologicals.* A drug or biological that is used in cancer therapy, including, but not limited to, a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, and a bisphosphonate if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(3) *Radiopharmaceutical drugs and biological products.* A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine services if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(4) *Other drugs and biologicals.* A drug or biological that meets the following conditions:

(i) It was first payable as an outpatient hospital service after December 31, 1996.

(ii) CMS has determined the cost of the drug or biological is not insignificant in relation to the amount payable for the applicable APC (as calculated under §419.32(c)) as defined in paragraph (b) of this section.

(b) *Cost.* CMS determines the cost of a drug or biological to be not insignificant if it meets the following requirements:

(1) *Services furnished before January 1, 2003.* The expected reasonable cost of a drug or biological must exceed 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(2) *Services furnished after December 31, 2002.* CMS considers the average cost of a new drug or biological to be not insignificant if it meets the following conditions:

(i) The estimated average reasonable cost of the drug or biological in the

category exceeds 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(ii) The estimated average reasonable cost of the drug or biological exceeds the cost of the drug or biological portion of the APC payment amount for the related service by at least 25 percent.

(iii) The difference between the estimated reasonable cost of the drug or biological and the estimated portion of the APC payment amount for the drug or biological exceeds 10 percent of the APC payment amount for the related service.

(c) *Limited period of payment.* CMS limits the eligibility for a pass-through payment under this section to a period of at least 2 years, but not more than 3 years, that begins as follows:

(1) For a drug or biological described in paragraphs (a)(1) through (a)(3) of this section—August 1, 2000.

(2) For a drug or biological described in paragraph (a)(4) of this section—the date that CMS makes its first pass-through payment for the drug or biological.

(d) *Amount of pass-through payment.* Subject to any reduction determined under §419.62(b), the pass-through payment for a drug or biological equals the amount determined under section 1842(o) of the Social Security Act, minus the portion of the APC payment amount that CMS determines is associated with the drug or biological.

[65 FR 18542, Apr. 7, 2000, as amended at 69 FR 832, Jan. 6, 2004; 69 FR 65863, Nov. 15, 2004]

§419.66 Transitional pass-through payments: Medical devices.

(a) *General rule.* CMS makes a pass-through payment for a medical device that meets the requirements in paragraph (b) of this section and that is described by a category of devices established by CMS under the criteria in paragraph (c) of this section.

(b) *Eligibility.* A medical device must meet the following requirements:

(1) If required by the FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA

in accordance with §§405.203 through 405.207 and 405.211 through 405.215 of this chapter) or another appropriate FDA exemption.

(2) The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part (as required by section 1862(a)(1)(A) of the Act).

(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital.

(4) The device is not any of the following:

(i) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1).

(ii) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).

(iii) A material that may be used to replace human skin (for example, a biological or synthetic material).

(c) *Criteria for establishing device categories.* CMS uses the following criteria to establish a category of devices under this section:

(1) CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

(2) CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

(3) Except for medical devices identified in paragraph (e) of this section, CMS determines the cost of the device is not insignificant as described in paragraph (d) of this section.

(d) *Cost criteria.* CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:

(1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.

(2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

(3) The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service.

(e) *Devices exempt from cost criteria.* The following medical devices are not subject to the cost requirements described in paragraph (d) of this section, if payment for the device was being made as an outpatient service on August 1, 2000:

(1) A device of brachytherapy.

(2) A device of temperature-monitored cryoablation.

(f) *Identifying a category for a device.* A device is described by a category, if it meets the following conditions:

(1) Matches the long descriptor of the category code established by CMS.

(2) Conforms to guidance issued by CMS relating to the definition of terms and other information in conjunction with the category descriptors and codes.

(g) *Limited period of payment for devices.* CMS limits the eligibility for a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years beginning on the date that CMS establishes a category of devices.

(h) *Amount of pass-through payment.* Subject to any reduction determined under §419.62(b), the pass-through payment for a device is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment amount for the device.

[66 FR 55856, Nov. 2, 2001, as amended at 67 FR 66813, Nov. 1, 2002; 70 FR 68728, Nov. 10, 2005]